

APPENDIX A

Listing of Claims

1. (Previously Amended) A urethral suppository for insertion into a female urethra, said suppository comprising:

a. a non-meltable base member having a surface and sized to prevent insertion of said base member into said urethra;

b. a non-meltable reinforcement having a length, said length having a first end and a second end, said first end attached to said base member and projecting from said base member; and

c. a meltable portion formed around at least a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said second end toward said first end, said meltable portion sized for insertion into said urethra.

2. (Original) The urethral suppository of claim 1 wherein said base member is shaped for handling by a user of said suppository.

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3. (Original) The urethral suppository of claim 1 wherein said base member is an ellipsoid having a major axis substantially perpendicular to the longitudinal axis of the reinforcement.

4. (Original) The urethral suppository of claim 3, wherein said ellipsoid is curved to promote maximal penetration of the meltable portion in the urethra.

5. (Original) The urethral suppository of claim 1 wherein the base member is grooved to facilitate handling by a user.

6. (Original) The urethral suppository of claim 1 wherein the surface of said base member is roughened to reduce slippage of suppository during insertion.

7. (Cancelled)

8. (Original) The urethral suppository of claim 1 wherein said base member is formed from one or more materials selected from the group consisting of synthetic polymer, urethane, cellulose, glass, metal, rubber, and cloth.

9. (Original) The urethral suppository of claim 1 wherein said reinforcement first end is embedded within said base member.

10. (Original) The urethral suppository of claim 1 wherein said reinforcement projects substantially perpendicular from said base member.

11. (Original) The urethral suppository of claim 1 wherein said reinforcement comprises a shape selected from the group consisting of rod, ratchet, helix, and cone.

C. 12. (Original) The urethral suppository of claim 11 wherein said shape is comprised of a lattice or mesh.

13. (Previously Amended) The urethral suppository of claim 1 wherein said reinforcement is formed from one or more materials selected from the group consisting of urethane, cellulose, glass, metal, rubber, and cloth.

14. (Original) The urethral suppository of claim 1 wherein said reinforcement is sized such that upon insertion of the suppository into the urethra, the second end of said reinforcement is contained entirely within the meltable portion.

15. (Original) The urethral suppository of claim 1 wherein the second end of said reinforcement extends outside the meltable portion.

16. (Currently Amended) The urethral suppository of claim 1 wherein ~~the female urethra has a urethral length and~~ the length of said reinforcement is in the range of about 40.0mm to about 80.0mm greater than the urethral length.

17. (Previously Amended) The urethral suppository of claim 16 wherein said reinforcement has a diameter in the range of about 0.5mm to about 2.0mm.

18. (Original) The urethral suppository of claim 1 wherein said reinforcement comprises one or more restraints formed along the portion of the length of the reinforcement on which the meltable portion is formed.

19. (Original) The urethral suppository of claim 18 wherein said one or more restraints are selected from one or more of the group consisting of protrusions, intrusions, and combinations thereof.

20. (Original) The urethral suppository of claim 19 wherein said protrusions have shapes selected from the group of shapes consisting of spheres, hemispheres, triangles, rectangles, plates, rods, and combinations thereof.

21. (Original) The urethral suppository of claim 19 wherein said intrusions have shapes selected from the group of shapes consisting of spheres, triangles, rectangles, plates, rods, and combinations thereof.

22. (Original) The urethral suppository of claim 1 wherein said meltable portion comprises one or more materials selected from the group consisting of theobroma oil and modified theobroma oil products, glycerinated gelatin, hydrogenated vegetable oils, cellulose, poly (vinyl alcohol), poly (vinylpyrrolidone), polyacrylamide, poly (ethylene glycol), poly (phospho urethanes), polyoxyl stearate and ethylenoxide polymers.

23. (Original) The urethral suppository of claim 1 wherein said meltable portion comprises one or more therapeutic agents selected from one or more of the group of agents consisting of antibiotics, antimicrobials, antifungals, analgesics, anesthetics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, mucous production inhibitors, hormones, and antispasmodics.

24. (Original) The urethral suppository of claim 1 wherein the diameter of the meltable portion formed around the second end is in the range of about 5 to about 12 millimeters.

25. (Original) The urethral suppository of claim 1 wherein the diameter of the meltable portion formed around the first end is in the range of about 4 to about 10 millimeters.

26. (Original) The urethral suppository of claim 1 wherein grooves are formed in said meltable portion.

27. (Original) The urethral suppository of claim 26 wherein said grooves are parallel to a longitudinal axis of the meltable portion.

28. (Original) The urethral suppository of claim 26 wherein said grooves are helical.

29. (Original) The urethral suppository of claim 26 wherein said grooves form a passage for liquid melted from said meltable portion.

30. (Currently Amended) The urethral suppository of claim 1 wherein ~~the female urethra has a urethral length and~~ said meltable portion has a length greater than about 4.5cm ~~less than the urethral length.~~

31. (Original) The urethral suppository of claim 1 wherein the length of said meltable portion is from about 2.5 cm to about 5.0 centimeters.

32. (Original) The urethral suppository of claim 1 wherein said meltable portion melts within about 2 minutes to about 60 minutes.

33. (Original) A urethral suppository for insertion into a female urethra, said suppository comprising:

a. a non-meltable base member having a surface and sized to prevent insertion of said base member into said urethra;

b. a non-melttable reinforcement having a length, a first end attached to the base and a second end distal from the base, said reinforcement projecting from the base and comprising a urethral segment extending from said first end and a bladder segment extending from said urethral segment and terminating in said reinforcement second end, said urethral and bladder reinforcement segments sized such that the urethral segment is contained substantially entirely in the urethra, and the bladder segment is contained substantially entirely in the bladder, when the suppository is inserted into the female urethra; and

c. a meltable portion formed around the entire length of said reinforcement, said meltable portion comprising a taper region formed around said reinforcement urethral segment and an extension region formed around the reinforcement bladder segment, said taper region meltable portion having a diameter which tapers toward said reinforcement first end.

C 34. (Original) The urethral suppository of claim 33 wherein said base member is shaped for handling by a user of said suppository.

35. (Original) The urethral suppository of claim 33 wherein said base member is an ellipsoid having a major axis substantially perpendicular to the longitudinal axis of the reinforcement.

36. (Original) The urethral suppository of claim 35, wherein said ellipsoid is curved to promote maximal penetration of the meltable portion in the urethra.

37. (Original) The urethral suppository of claim 33 wherein the surface of said base member is grooved to facilitate handling by a user.

38. (Original) The urethral suppository of claim 33 wherein the surface of said base member is roughened to reduce slippage of suppository during insertion.

39. (Original) The urethral suppository of claim 33 wherein said base member is sized to fit within the labia minora of a patient.

40. (Original) The urethral suppository of claim 33 wherein said base member is formed from one or more materials selected from the group consisting of synthetic polymer, urethane, cellulose, glass, metal, rubber, and cloth.

41. (Original) The urethral suppository of claim 33 wherein said reinforcement projects substantially perpendicular from said base member.

42. (Original) The urethral suppository of claim 33 wherein said reinforcement comprises a shape selected from the group consisting of rod, ratchet, helix, and cone.

43. (Original) The urethral suppository of claim 42 wherein said shape is comprised of a lattice or mesh

44. (Original) The urethral suppository of claim 33 wherein said reinforcement is formed from one or more materials selected from one or more of the groups consisting of urethane, cellulose, glass, metal, rubber, and cloth.

45. (Original) The urethral suppository of claim 33 wherein said reinforcement comprises one or more restraints formed along said portion of said length of said reinforcement.

46. (Original) The urethral suppository of claim 45 wherein said restraints are selected from one or more of the group consisting of protrusions and intrusions.

47. (Original) The urethral suppository of claim 46 wherein said protrusions are selected from one or more of the group of shapes consisting of spheres, hemispheres, triangles, rectangles, plates, and rods.

48. (Original) The urethral suppository of claim 46 wherein said intrusions are selected from one or more of the group of shapes consisting of spheres, hemispheres, triangles, rectangles, plates, and rods.

49. (Original) The urethral suppository of claim 33 wherein said meltable portion comprises one or more materials selected from the group consisting of theobroma oil and modified theobroma oil products, glycerinated gelatin, hydrogenated vegetable oils, cellulose, poly (vinyl alcohol), poly (vinylpyrrolidone), polyacrylamide, poly (ethylene glycol), poly (phospho urethanes), polyoxyl stearate and ethylenoxide polymers.

50. (Original) The urethral suppository of claim 33 wherein said meltable portion comprises one or more therapeutic agents selected from one or more of the group of agents consisting of antibiotics, antimicrobials, antifungals, analgesics, anesthetics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, mucous production inhibitors, hormones, and antispasmodics.

C 51. (Original) The urethral suppository of claim 33 wherein the maximum diameter of the meltable portion formed around the urethral region is in the range of about 5 to about 12 millimeters.

52. (Original) The urethral suppository of claim 33 wherein the diameter of the meltable portion formed around the first end is in the range of about 4 to about 10 millimeters.

53. (Original) The urethral suppository of claim 33 wherein grooves are formed in said meltable portion.

54. (Previously Amended) The urethral suppository of claim 53 wherein said grooves are parallel to a longitudinal axis of the meltable portion.

55. (Previously Amended) The urethral suppository of claim 53 wherein said grooves are helical.

56. (Previously Amended) The urethral suppository of claim 53 wherein said grooves form a passage for liquid melted from said meltable portion.

57. (Original) The urethral suppository of claim 33 wherein the length of said taper region is from about 2.5 cm to about 5.0 centimeters.

58. (Original) The urethral suppository of claim 33 wherein upon insertion, said meltable portion melts within about 2 minutes to about 60 minutes.

59. (Currently Amended) The urethral suppository of claim 33 wherein ~~the female urethra has a urethral length and~~ the length of said reinforcement is in the range of about 40.0mm to about 80.0mm~~greater than the urethral length.~~

60. (Currently Amended) The urethral suppository of claim 59 wherein said reinforcement has a diameter in the range of about 0.5mm to about 2.0mm~~is sized for minimal or no contact with the neck of the bladder.~~

C₁ 61. (Previously Amended) A method for delivering one or more therapeutic agents to the female urinary tract, said method comprising the steps of: a. inserting the suppository of claims 1 or 33 into the urethra of a female patient; b. waiting a sufficient period for said suppository to deliver one or more therapeutic agents to said urinary tract; and c. removing the non-meltable reinforcement from the urethra.

62. (Original) The method of claim 61 wherein the period ranges from about 1 minutes to about 10 hours.

63. (Original) The method of claim 61 wherein the period ranges from about 2 minutes to about 2 hours.

64. (Original) The method of claim 61 wherein said insertion step comprises grasping the suppository by the non-meltable base member, and positioning the suppository into the urethra wherein the base member sits completely within the labia minora.

65-72. (Withdrawn)

73. (Previously Added) The urethral suppository of claim 1 wherein said reinforcement has a length in the range of about 25.0mm to about 80.0mm.

74. (New) The urethral suppository of claim 1 wherein the length of said reinforcement is in the range of about 25.0mm to about 40.0mm.

75. (New) The urethral suppository of claim 33 wherein the length of said reinforcement is in the range of about 25.0mm to about 40.0mm.

APPENDIX B

Ten Replacement Sheets of Drawings